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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,262	03/15/2004	Aleksandra Niedzwiecki	RATH-012	2275

7590
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01/03/2007

EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/801,262

Applicant(s)

NIEDZWIECKI ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 2, 9, 12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In each case, the claim appears to require fewer components than the claim on which it is dependent. Claim 2 does not indicate the amount of the acceptable component; Claims 9 and 12 do not indicate that composition contains said component, copper, selenium or manganese.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

If it was the Applicant's intent that the individual components be modified then the claims should not indicate that the dose of the composition contains but the individual components are present in the claimed amounts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boulos et al. (US Pat. 6,914,073) in view of Murad (US 2002/0127256).

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Boulos et al. disclose composition for benefiting cardiovascular health, including slowing the progression of atherosclerosis containing lysine, proline, arginine, Vitamin C, magnesium, green tea, selenium, copper and manganese which can be administered orally as a tablet or capsule which are formulated using various excipients (Column 3, lines 40-55, Column 6, lines 10-20, 40-46, Column 7, lines 65-67, Column 9, lines 8-26, Columns 11, 12). It is disclosed that the composition can also contain Vitamin A, Vitamin D, Thiamin, Riboflavin, Niacin, Biotin and Pantothenic Acid (Column 6, lines 30-38).

Gavish et al. disclose that high levels of lipoprotein (a) is associated with atherosclerotic disease and that administration of N-acetylcysteine was effective in lowering plasma levels of lipoprotein (a) (Abstract).

Tedeschi et al. disclose that both Green Tea and vitamin C have antiinflammatory activity (Page 435).

The prior art discloses the combination of lysine, proline, arginine, Vitamin C, magnesium, green tea, selenium, copper and manganese for slowing the progression of atherosclerosis and benefiting cardiovascular health. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the treatment of inflammation or the addition of acetyl-cysteine. However, the prior art amply suggests the same as the prior art discloses that acetyl cysteine is effective in lowering high lipoprotein (a) plasma levels, which is a risk factor for atherosclerosis and that Vitamin C and Green Tea have anti-inflammatory activity. As such, it would have been well within the skill of and one of ordinary skill in the art would have expected that the combination of acetyl cysteine would add to the anti-

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atherosclerotic activity of the prior art composition and that the prior art composition would also be effective in treating inflammation.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

Contrary to the Applicant's argument, the Examiner has provided the motivation to modify or combine the references as indicated above. The motivation to combine the references need not be the same as the Applicant's or even be explicitly stated in any one of the references. Further, there is a reasonable expectation of success as the prior art discloses that the composition would the combination of acetyl cysteine would add to the anti-atherosclerotic activity of the prior art composition and that Green Tea and Vitamin C are effective in treating inflammation. Finally, the evidence of unexpected activity is not commensurate in scope with the claimed invention. The experiments are with respect to a specific embodiment and effects on IL-6, however, the claims are not limited to the same.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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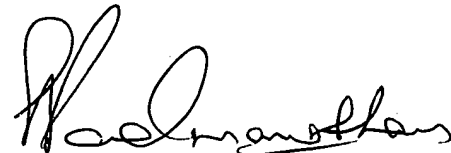
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
December 26, 2006



GREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER